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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,989	02/20/2004	Richard J. Glynne	2124.018US1	4374

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,989	GLYNNE ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3, 5-10, 12, 13 and 67, drawn to a non-human mammalian animal comprising a non-naturally occurring mutation in a sensin gene, wherein said mutated sensin gene is expressed as a cDNA having substantial sequence homology with SEQ ID No. 1 or said mammal are mice expressing a cDNA encoding the protein of SEQ ID No. 5, a colony of said non-human mammal, and a method of making said non-human mammal, classified in class 800, subclasses 14 and 21.

II. Claims 4-9, 11-13 and 67, drawn to a non-human mammalian animal comprising a non-naturally occurring mutation in a sensin gene, wherein said mutated sensin gene is expressed as a cDNA having substantial sequence homology with SEQ ID No. 2 or said mammal are mice expressing a cDNA encoding the protein of SEQ ID No. 6, a colony of said non-human mammal, and a method of making said non-human mammal, classified in class 800, subclasses 14 and 21.

III. Claims 16-26 and 41-43, drawn to a method for screening for modulators of motor activity in a mammal, such as a mammal comprising a mutation in a sensin gene, by contacting one or more mammal with one or more test compound, such as nucleic acids, antisense molecules and RNAi molecules, and determining whether said test compound alter a sensin-mediated motor-related phenotype, wherein said mutated sensin gene is expressed as a cDNA having substantial sequence homology with SEQ ID No. 1 or said mammals are mice expressing a cDNA encoding the protein

of SEQ ID No. 5, classified in classes 800 and 435, subclasses 3 and 4, respectively.

IV. Claims 16-18, 20-25, 27, 41, 42 and 44, drawn to a method for screening for modulators of motor activity in a mammal, such as a mammal comprising a mutation in a sensin gene, by contacting one or more mammal with one or more test compound, such as nucleic acids, antisense molecules and RNAi molecules, and determining whether said test compound alter a sensin-mediated motor-related phenotype, wherein said mutated sensin gene is expressed as a cDNA having substantial sequence homology with SEQ ID No. 2 or said mammals are mice expressing a cDNA encoding the protein of SEQ ID No. 6, classified in classes 800 and 435, subclasses 3 and 4, respectively.

V. Claims 29-32 and 34-39, drawn to a method for screening for modulators of motor activity in a mammal by contacting one or more mammals with one or more test compounds and determiming whether said test compound alter expression of a mutated or wild-type sensin gene, wherein said mutated sensin gene is expressed as a cDNA having a substantial sequence homology with SEQ ID No. 1 or said mammals are mice expressing a cDNA encoding the protein of SEQ ID No. 5, classified in classes 800 and 435, subclasses 3 and 6, respectively.

VI. Claims 29-31, 33-38 and 40, drawn to a method for screening for modulators of motor activity in a mammal by contacting one or more mammals with one or more test compounds and determiming whether said

test compound alter expression of a mutated or wild-type sensin gene, wherein said mutated sensin gene is expressed as a cDNA having a substantial sequence homology with SEQ ID No. 2 or said mammals are mice expressing a cDNA encoding the protein of SEQ ID No. 6, classified in classes 800 and 435, subclasses 3 and 6, respectively.

VII. Claims 46 and 48, drawn to a method for determining the level of a sensin polypeptide in a sample by assaying for said sensin polypeptide with an antibody, wherein said antibody binds to the protein of SEQ ID No. 5, classified in class 435, subclass 7.1.

VIII. Claims 47 and 48, drawn to a method for determining the level of a sensin polypeptide in a sample by assaying for said sensin polypeptide with an antibody, wherein said antibody binds to the protein of SEQ ID No. 6, classified in class 435, subclass 7.1.

IX. Claims 49-52, drawn to a method for diagnosing a motor deficit in a subject by determining whether said subject comprises a mutation in a sensin nucleic acid sequence, and a kit for determining whether a sample comprises a mutation in a sensin nucleic acid sequence, classified in class 435, subclasses 6 and 810.

X. Claims 53-55, drawn to an isolated sensin polypeptide or an isolated polypeptide comprising at least 15 amino acid residues of one of SEQ ID Nos. 5-11, classified in class 500, subclass 350.

XI. Claims 56-61, drawn to an isolated sensin nucleic acid or an isolated nucleic acid encoding a polypeptide comprising at least 15 amino acid

residues of one of SEQ ID No. 5-11, a recombinant vector comprising said nucleic acid, and a host cell comprising said vector, classified in classes 536 and 435, subclasses 23.5 and 320.1.

XII. Claim 62, drawn to an antibody specifically binds against a sensin polypeptide, classified in class 530, subclass 387.1.

XIII. Claim 63, drawn to a method of identifying one or more gene related to mammalian motor function by introducing one or more mutation into genome of a mouse having a nucleic acid encoding a mutated sensin gene, identifying the mutation that affect sensin-mediated motor-related phenotype of said mouse, classified in classes 800 and 435, subclasses 3 and 6, respectively.

XIV. Claims 64-66, drawn to a method comprising expressing in one or more cells of a subject a sensin polypeptide encoded by an expression construct, classified in class 514, subclass 44.

XV. Claim 68, drawn to a method of identifying one or more gene related to motor function by determining whether said genes encode polypeptides that bind to an isolated sensin polypeptide, classified in class 435, subclass 7.8.

Claims 1 and 2 link(s) inventions I and II. Claims 14 and 15 link inventions III and IV. Claim 28 links inventions V and VI. Claim 45 links inventions VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 14, 15, 28 and 45. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and

any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct from each other because they are drawn to different non-human mammals comprising different genes that differ in their nucleotide sequences, encoded amino acid sequences and biological function of the encoded protein: mouse sensin vs. human sensin. The resulting phenotype of those non-human mammals expressing different polypeptides would differ dramatically from each other. A search for group I does not require a search for group II, and vice versa. There is serious burden to search for both groups I and II. Thus, groups I and II are patentably distinct from each other. Similarly, groups III and IV are patentably distinct from each other, and groups V and VI are patentably distinct from each other. Groups VII and VIII are patentably distinct from each other for the same reasons.

Groups X-XII are distinct because they are drawn to different compositions that differ in chemical structures, physical properties and biological functions: polypeptides,

nucleic acids, and antibodies. A polypeptide and an antibody are structurally distinct molecules. A polypeptide is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody is defined in terms of its binding specificity to a small structure within a polypeptide. Polypeptides and antibodies are composed of amino acids, however, polynucleotides are composed of nucleic acids, which are distinct from polypeptides and antibodies. The search for polypeptides, antibodies and polynucleotides are not coextensive. They have different classifications and require separate search. Thus, groups X-XII are patentably distinct from each other.

Groups I-VI and groups X-XII are distinct because they are drawn to different compositions that differ in chemical structures, physical properties and biological functions: non-human mammals vs. polypeptides, nucleic acids, and antibodies. A non-human mammal differs dramatically from polypeptide, polynucleotides and antibodies morphologically and physiologically. The search for non-human mammals does not require a search for polypeptides, antibodies and polynucleotides. They have different classifications and require separate search. Thus, groups I-VI and groups X-XII are patentably distinct from each other.

Inventions XII and inventions VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody of group XII can be used purify a polypeptide or to treat a disease as opposed to determine the level of a sensin polypeptide in a sample.

Inventions XI and inventions XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of group XI can be used as a probe or to produce a recombinant protein in vitro as opposed to introduce into a subject for expression.

Inventions X and inventions XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the sensin polypeptide of group X can be used to produce an antibody against said sensin polypeptide as opposed to polypeptide binding assay.

Group X is unrelated to groups VII-IX, XIII and XIV because the product of group X is not used or otherwise involved in the process of group VII-IX, XIII and XIV.

Group XI is unrelated to groups VII-IX, XIII and XV because the product of group XI is not used or otherwise involved in the process of group VII-IX, XIII and XV.

Group XII is unrelated to groups IX and XIII-XV because the product of group XII is not used or otherwise involved in the process of group IX and XIII-XV.

Groups I-II, groups III-IV, groups V-VI, groups VII-VIII, group IX, group XIII, group XIV and group XV are distinct from each other because they are drawn to materially different methods that differ at least in objectives, method steps, reagents

and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, groups I-II, groups III-IV, groups V-VI, groups VII-VIII, group IX, group XIII, group XIV and group XV are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

SHIN-LIN CHEN
PRIMARY EXAMINER